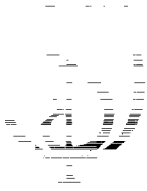


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**U.S. Poultry & Egg
ASSOCIATION**

1530 Cooleedge Road
Tucker, GA 30084-7303, U.S.A.
Telephone: 770/493-9401
Facsimile: 770/493-9257
www.poultryegg.org

Chairman
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August 8, 2000

TO: USDA/FSIS Hearing Clerk
300 12th Street, S.W.
Room 102 Cotton Annex
Washington, D.C., 20250-3700

FDA Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

The follow comments are submitted regarding FSIS Docket No. 98-045N4 or FDA Docket No. 00N-0504 entitled "Egg Safety; Current Thinking. Papers on Egg Safety National Standards."

We appreciate the opportunity to hear your current thinking as you proceed to develop the proposed rule on Egg Safety; Farm To Table. Hopefully you will consider our comments, presented below, as you finalize the proposed rule. The headings are taken from the outline distributed at the meeting on July 31, 2000 in Washington, D.C.

1. USE OF SALMONELLA - NEGATIVE FEED:

There is no evidence to indicate that feed has been a factor in the problem of Salmonella enteritidis (SE) illnesses related to eggs. It has been discussed in expert circles, and the consensus is that feed has no significant role in determining the SE status of a layer flock.

Therefore, while FDA certainly has the authority to require Salmonella-negative feed, the egg safety issue is about SE, not the other over 2200 serotypes of Salmonellae. The feed testing burden to meet any requirements that may be contained in the new regulation will overload the laboratories and detract from the issue at hand which is to reduce the SE illnesses related to eggs. This provision on feed should not be part of the proposed rule, either for all Salmonellae or for SE because it will have no measurable effect on achieving the goal of reducing illnesses from eggs. Eggs have not been a significant

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source of illnesses from the other Salmonellae since the Egg Products Act prohibited the sale of cracked or dirty eggs to consumers and required the pasteurization of liquid eggs.

2. RODENT AND PEST CONTROL PROGRAM:

Many are convinced, based on the evidence in Pennsylvania acquired during the SE control program, from subsequent research and surveys, that rodents may have a major, if not the most important, role in the SE problem at the farm level. They likely have a similar role in the home and institutional settings.

Hopefully, government will provide assistance to the industry in the form of research and educational literature to help all components of the food industry deal with this problem. We heartily endorse the inclusion of the rodent control provision in the proposed rules.

3. REFRIGERATED STORAGE (45°F) OF EGGS HELD ON THE FARM FOR MORE THAN 36 HOURS AFTER LAYING:

This provision appears acceptable until you consider the reality of current practices. Individuals with small flocks who operate under contract with a larger producer/processor have their eggs picked up at the farm and transported to the processing plant two or three times a week. Even if they were picked up on Monday, Wednesday and Friday, it means that they would not meet this requirement and they would have to build a cooler room capable of maintaining 45°F. Even if they were picked up five days a week, the weekend schedule would mandate that they construct a 45°F cooler room. The only way to comply with the 45°F/36 hour provision will be to have daily pickup of eggs. We predict that the requirement for a 45°F cooler will pose a significant economic hardship for many of those small operations and force them out of business.

If the intent of this provision is to get eggs into a 45°F environment within 36 hours of being laid, it will require all inline producers/processors to operate seven days a week.

4. COVERAGE: PRODUCERS WHO PROVIDE EGGS FOR THE TABLE EGG MARKET MUST COMPLY WITH ALL REQUIREMENTS:

We assume that this means even a small egg producer with less than 3000 hens who provides eggs for the small country store will be included in the proposed regulation.

We don't have a problem with this because even though such small producers provide only 1% or less of all eggs, it may be that rodent and other husbandry problems could result in their having a much higher rate of SE. This could be very important in reducing SE human illnesses. To not include them in the regulation may negatively impact the commercial egg industry which is being judged by the total of egg related illnesses and not just those related to eggs from large operations.

5. VERIFICATION OF THE SE RISK REDUCTION PLAN:

The flow chart shows that the environments of 40-45 week-old layers and molted hens at 25 weeks after molting will be sampled and cultured for SE. As you formulate this portion of the proposed rule, please recognize the huge workload and cost that will result, depending on the number of samples you require for each house. It may well be that the NVSL-certified laboratory infrastructure will be incapable of handling such a marked increase in samples. It would be appropriate for government to reimburse for the cost of this mandated testing.

Related to the subject of house sampling and culturing, this Association has funded the production and duplication of a set of three videotapes: layer house sampling, laboratory culturing of Salmonella, and Salmonella serology. The first two have been completed and widely distributed free of charge. The third is in the final completion phase. These tapes were prepared under contract with a commercial videotape company with Andy Rhorer of the USDA/NPIP and Dr. Doug Waltman of the Georgia Poultry Laboratory providing the technical expertise. It is clear that there must be a significant training effort to get this sampling program underway. These tapes should be helpful toward that end.

This Association mounted a very successful training effort when FSIS proposed their HACCP-based inspection programs for the broiler processing industry. The 2-3 day training course was given in many parts of the country, was well attended and was probably responsible for the industry's ability to transition to the new HACCP system with minimal difficulty. A similar type of training program will be needed by the egg industry, specifically directed to the on-farm egg producers and egg processors.

6. ADMINISTRATION OF THE SE RISK REDUCTION PLAN:

It is our understanding that while the FDA is responsible for the on-farm portion of the Egg Safety Plan, they will contract with state officials to carry out the inspections and certifications of compliance. Such a plan will likely work out very well in some states, but not in others. There will be great differences in the levels of knowledge, experience and ability to carry out that responsibility. Such a contract system could cause problems due to the variation in inspection from state to state.

7. DIVERSION:

Throughout the documents related to the President's Plan on Egg Safety, there is the frequent mention of maintaining a "level playing field" with a standard national program. Well, the diversion requirement without compensation unlevels that playing field. For example, when a company has a layer house that tests positive environmentally and then at least one egg subsequently tests positive, the eggs from that house will be required to be diverted to pasteurization, most likely at a breaker facility. A large company that has a breaker/pasteurization plant as part of its infrastructure will simply divert eggs from their positive flocks to pasteurization, substituting them for the eggs produced and previously intended for breaking and pasteurization. The action of diversion will pose little or no economic hardship on such a large company.

On the other hand, a company without a breaking/pasteurization plant will have to go on the open market and try to sell the diverted eggs under a "SE-positive, must sell" economic cloud. The price they will get will be well below table egg prices if they can be sold at all. Without at least partial off-setting indemnification, that company could soon be in serious economic difficulty and fail. Should a layer operation in Hawaii test positive and have to divert the eggs, there is not a single breaker/pasteurization plant on the islands. California has reported that they have very limited breaking/pasteurization capacity. Other geographic areas of the country also have very limited access to pasteurization capabilities.

It is clear that companies without in-house pasteurization capabilities may fail if required to divert a significant portion of their eggs and they receive no indemnification to at least partially off-set the loss. We understand that there is no presently available mechanism to fund such an indemnification program, but that is the only way to preserve the economic health of the smaller companies without their own breaking/pasteurization plants.

8. RECORDKEEPING REQUIREMENTS:

The regulation should be very comprehensive and specific in exactly which records are to be kept, in what format and for how long. It would be unfortunate for producers to be penalized because of a misunderstanding of what is required by the regulation. If forms are provided, they should be simple and easy to understand. Unnecessary information, not closely related to egg safety, should not be required.

9. PROHIBITION OF REPACKING FOR RETAIL SALE:

We applaud this proposed action and we encourage that it apply at all levels including the retail store where repackaging to replace broken eggs is not uncommon. It bypasses the dating and source identification of the eggs. Those eggs should only go for pasteurization.

Previously cartoned or cased eggs that have never left the processing plant should not be allowed to be rewashed and repackaged with a later date. This could result in old eggs going to the consumer with erroneous dating. This may not be a frequent practice, but it should be prohibited and the eggs sold as dated or shipped for pasteurization.

10. SERVE AT-RISK CONSUMERS:

We have long sought that this provision for substituting pasteurized eggs for such facilities be made mandatory. It will essentially end the mortality associated with egg-related SE. It has been a long time coming, but we believe it will be very beneficial if it is properly enforced. The distinction between "egg-borne" and "egg-related" illnesses may be important here to assure that contamination of SE-free pasteurized egg products does not occur in the kitchens that serve the at-risk consumers.

11. SERVE THE GENERAL PUBLIC:

We don't really understand what is meant by the outline under this heading. We don't recommend that raw or undercooked eggs be consumed by anyone unless they have been previously treated by pasteurization or perhaps irradiation. We assume that you mean that you will provide information on appropriate times/temperatures of egg-containing foods to assure inactivation of all bacteria that may be in the dish. Such information will be helpful.

In summary, we don't want to see the Salmonella-negative feed requirement "piggy-backed" onto this Egg Safety regulation. We urge moderation in the number of environmental samples required to keep from "swamping" the labs and we would like to see government funding of the mandatory tests. We want you to realize the economic impact of the 36-hour-45°F requirement, and we request that the recordkeeping requirements be simple and straightforward, free of all "governmentese."

We are concerned about the small flock (<3000) exemptions because they could cause a disproportionate share of illnesses which will reflect negatively on the egg industry.

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We applaud the repacking prohibition proposal, and we request that our earlier request for a less frightening but effective label be seriously considered instead of the label you previously proposed. Eggs are such an important part of the diets of children and it would be tragic if their mothers were made afraid to buy them because of inflammatory labeling.

While the program is presented as a "farm to table program," it is clearly placing the burden, almost all of it, on the producer at the farm and processor level. There is very little in the plan to deal with the user abuse and improper cooking at the commercial kitchen level which is where most of the problems occur.

We suggest that you consider extending the pasteurized egg product requirement to include institutions like prisons, colleges, etc., where large numbers of eggs are hand-broken and pooled. Breakfast buffets that serve large pans of soft scrambled eggs would be another situation where the substitution of pasteurized product for hand-breaking and pooling would be appropriate.

Unless adequate attention is directed toward the commercial/institutional abuse that occurs, the egg industry can supply SE free eggs and "egg-related" illness will continue to occur. The liquid egg will be contaminated, temperature-abused and improperly cooked. Inoculation will be from rodent contaminated utensils/equipment and SE-infected/shedding workers. If the program is going to be truly "farm to table," you have more work to do, closer to the table.

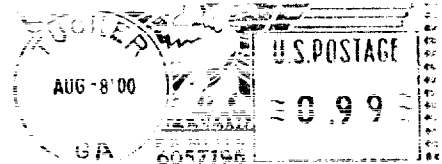
We appreciate having the opportunity to learn what you are thinking on these issues and having an opportunity to comment before you develop the proposed rule. If you wish clarification on any of the comments in this communication, please contact Don Dalton or Charles Beard at (770) 493-9401.

Sincerely,



Don Dalton
President, U.S. Poultry & Egg Association
ddalton@poultryegg.org

DD/jal



U.S. Poultry & Egg Association
1530 Cooledge Road
Tucker, Georgia 30084-7303

FDA Dockets Management Branch
(HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

First Class Mail